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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,727	07/08/2002	Hubert Rein	228.1010	8812
20583	7590	04/22/2008	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			ROGERS, JAMES WILLIAM	
			ART UNIT	PAPER NUMBER
			1618	
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			04/22/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No. 09/980,727	Applicant(s) REIN ET AL.	
Examiner JAMES W. ROGERS	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 12 November 2007.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,4-6,10,16-18 and 20-32 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,4-6,10,16-18 and 20-32 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
- Certified copies of the priority documents have been received.
 - Certified copies of the priority documents have been received in Application No. _____.
 - Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/12/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1,4-6,10,16-18,20-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically claim 1 recites the new limitation that co-extruding through an extruder a composition comprising a **dry mixture** of at least one pharmaceutically active agent and starch, the examiner could not find support within the specification that the mixture is dry prior to co-extrusion. The only instance of a dry mixture the examiner could find was at page 5 lines 14-16 which states water in concentrations up to 15% should be added to the thoroughly mixed dry formulation. Thus this would hardly constitute support within the specification for using a dry mixture before co-extrusion; rather the passage actually seems to teach against using a dry mixture.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1618

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,5-6,10,16-17,25-26,31-32 are rejected under 35 U.S.C. 102(a) as being anticipated by Federico (WO/9934780, cited by applicants), this new rejection was necessitated by applicants newly disclosed IDS filed 11/12/2007.

Federico teaches a method for blending one or several active ingredients including pharmaceuticals dispersed within a matrix of thermoplastic starch and an intermediate layer or phase connecting layer by melt extrusion, the active ingredient is coated/capsulated at temperatures preferably between 30-60°C, below applicants claimed upper limit. See abstract. Regarding the limitation that the matrix is water-insoluble, it is inherent that since the matrix was processed in the same manner and contains the same substance the property of the matrix will be the same as applicants claimed invention. Regarding the limitations on the release of the active following the lapidus rule or that the release is over 24 hours, it is inherent that since the matrix of Federico is the same as applicants claimed invention the release profile will be the same since the same composition will have the same properties.

Response to Arguments

Art Unit: 1618

Claims 1, 4-6, 10, 16-18, 20 and 22-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Lentz *et al.*, for the reasons set forth in the office action filed 05/11/2007.

Applicant's arguments filed 11/12/2007 have been fully considered but they are not persuasive. Applicants assert the only example within Lentz which employed co-extrusion of starch and an active led to a foamed product not a vitrified product. Applicants further argue that the active ingredient within Lentz is not processed with the starch but is merely combined with the starch after processing. Furthermore applicants assert Lentz product is soft and rubbery and is thus above the glass transition temperature. Furthermore applicants assert that Lentz prefers that the process to heat the composition is above the glass transition temperature, and this is in contrast to applicant's invention in which the composition is vitrified, thus applicants state its temperature never exceeded the glass transition temperature.

The relevance of these assertions is unclear. In regards to applicants assertion that the only co-extrusion process within the examples is a foamed product and the product within the examples is soft and rubbery, these arguments are not found persuasive since the examples within Lentz were given solely for the purpose of illustration and were not to be construed as being limiting to their invention since many variations are possible without departing from the spirit and scope of the invention. Clearly Lentz describes that the starch could be in several physical forms depending on the processing temperature including melts and/or thermoplastic materials which would not be physically rubbery or soft, rather upon cooling they would be glass-like. Example

Art Unit: 1618

18 is only one very limited embodiment of the Lentz reference, a vaginal suppository and clearly is not limiting for the entire scope of the reference which teaches numerous final products besides the narrow product described within claim 18. In regards to applicant's assertion that the active ingredient is not processed with starch, this assertion is false, Lentz clearly teaches that the active ingredient may be added to the starch prior to destructurezation process (the processing step of the starch). See page 13 lines 5-22. Regarding applicants statement that their product is never raised above the glass transition temperature, firstly this argument would seem to be of little relevance since applicants do not recite such a limitation on the temperature within claims 1 or 25. Secondly as stated in the previous office actions Lentz teaches a range of temperatures to process the starch and specific examples within the experimental section describe processes that are within applicants claimed temperature range. It is also noted by the examiner that claim 6 states the shear force, temperature and pressure are modified to achieve glass transition of the starch, thus it would appear that applicants matrix should be processed at the glass transition temperature. Thus it is inherent that since the processing could use the same a temperature within applicants claimed range and the technique of co-extrusion was taught within the reference one of ordinary skill in the art at the time of applicants claimed invention would have immediately envisaged applicants claimed invention since the temperature and the technique of processing starch in combination with an active was taught by Lentz.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 4-6, 10, 16-18, and 20-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz *et al.*, for the reasons set forth in the office action filed 05/11/2007.

Response to Arguments

Applicant's arguments filed 11/12/2007 have been fully considered but they are not persuasive. Applicants assert the examiner was misguided in applying MPEP §§ 2111 and 2123 to mean that the examiner can reasonably create a teaching by extrapolating a disclosed embodiment to a broader teaching without any further guidance. Applicants assert that the processing temperature range to which the examiner is citing means the entire process occurs at temperatures encompassing any temperature between 80°C to 240°C, but rather means that the entire process occurs at temperatures encompassing 80°C to 240°C, never just 80°C or 130°C or 240°C. Applicants assert the reference is referring to the range of temperatures of the extruder, the temperatures varying at different locations of the extruder. Applicants assert there are no details within the specification on how co-extrusion is carried out unless it is carried out by the same method that Lentz uses to extrude the starch alone. Applicants assert one such teaching is example 18 which does not provide details of co-extrusion and it teaches co-extrusion of not starch but molecularly dispersed starch (MDS) with an active. Applicants further assert that the result of claim 18 was a foamed rubbery product and not vitrified as required within the claims. Applicants assert Lentz does not

Art Unit: 1618

suggest a modification of the orifice of the extruder to be below 100°C at normal pressure, thus applicants surmise it is unreasonable for the examiner to extrapolate the disclosure of Lentz to suggest the co-extrusion of starch and an active agent at a die temperature less than 100°C. Applicants further assert in regards to the examiners last action that example 11 uses a preferred temperature range of 110°C to about 100°C but this process uses MDS not native starch. Applicants lastly submit that the last declaration of Dr. Rein does cover the entire breadth of the claims because the experiments from the specification disclose the full temperature profile claimed and Dr. Rein provided other experiments with die temperatures of 97°C, 100°C, 102°C and 114°C.

Firstly, the examiner respectfully disagrees in regards to applicants assertion that the examiner has extrapolated a broader meaning for the recitation of the temperature range cited throughout Lentz to mean that any temperature between 80-240°C for the orifices temperature could be selected and that this is in reference to the entire range of temperatures within the extruder. Firstly there are two specific examples in figure 10 in which the processing temperature for the controlled release formulation was 70°C and 100°C within applicants claimed range, these two examples show that contrary to applicants assertion the processing was carried out at either a constant temperature or at least a final temperature that is below applicants claimed upper limit. Thus applicant's assertion above that the temperature range is merely referring to the range of the entire extrusion process is not found persuasive since the examples clearly demonstrate that the processing temperature for at least two examples was below applicants claimed

Art Unit: 1618

upper limit. Applicant's assertion that there are no details within the specification on co-extrusion with an active besides example 18 is also not persuasive, clearly as recited in the previous office actions and above Lentz discloses co-extrusion of both the active and starch together during processing. The examples within Lentz such as example 18 were given solely for the purpose of illustration and were not to be construed as being limiting to their invention since many variations are possible without departing from the spirit and scope of the invention. Applicants assertion regarding example 11 which they purport to show that Lentz uses MDS starch when the temperature was about 110°C to about 100°C is also not found persuasive because once again applicants are interpreting the examples to be limiting to the scope of the invention of Lentz, when clearly the reference does describe processing the starch and active together, before the formation of MDS. Regarding applicants last assertion that the declaration and specification does cover the entire breadth of the claims, this is not found persuasive because the specifications examples only use 3 specific temperatures 65, 80 and 95 °C, while applicants declaration performed the experiment at temperatures of 80-80-80 and die temperatures at the high end of the claimed temperature limit of 97 and 100 °C. Because only a few examples was given by the applicant to show the results that would demonstrate patentability over the prior art, it is difficult to see how this properly illustrates results that are unexpected over what has been broadly taught by Lentz *et al.*

Conclusion

No claims are allowed at this time.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you

Art Unit: 1618

have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618

Application Number



Application/Control No.

09/980,727

Applicant(s)/Patent under Reexamination

REIN ET AL.

Examiner

JAMES W. ROGERS

Art Unit

1618